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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,306	11/07/2000	Li-Wei Hsu	205032000400	1255

25225 7590 12/24/2003

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/708,306	HSU ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-20 and 25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-20 and 25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/03 has been entered.

Amendment Entry

2. Applicant's amendment and response filed 8/7/03 in Paper No. 10 is acknowledged and has been entered. Claim 14 has been amended. Currently, claims 14-20 and 25-31 are pending and are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 102/103

3. In light of Applicant's amendment, the rejection of claims 14, 15, 17, 19, 20, and 25-27 under 35 U.S.C. 102(e) as being anticipated by Burmer (US 6,087,103) is hereby, withdrawn.

4. In light of Applicant's amendment, the rejections of claims 16, 18, and 28-31 under 35 U.S.C. 103(a) as being unpatentable over Burmer (US 6,087,103) in view of

Baek et al. (Agricultural Chemistry and Biotechnology, April 1998 (Abstract)) or Verma et al. (Journal of Medicinal and Aromatic Plant Sciences, September 1997), and in view of Kutsuna et al. (Journal of the Pharmaceutical Society of Japan, November, 1988) (Abstract)), are hereby, withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 14, 15, 17, 19, 20, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US Patent 6,087,103) in view of Upadhyay et al. (US Patent 5,962,515).

Burmer discloses a method and kit to screen compound arrays (ligands), i.e. small organic molecules, extracted from plant. The compounds bind selectively to a target protein (see column 8, lines 12-65 and column 15, lines 8-24). The method is used to screen and detect for binding of a labeled target to any of the compound arrays. The compounds are each incorporated into a different location (ligand address) that corresponds to a tag having a known address identified by reference to a matrix on a solid support (a well on a microtiter plate) and a corresponding location on a membrane (plastic microtiter plate) (see column 11, lines 16-64). The compound libraries are arrayed spatially in the matrix (see column 1, line 61 to column 2, line 26, column 3, lines 39-42, and column 4, lines 37-42). The compounds and target are contacted, incubated, washed with a buffer to remove unbound components, then detected for any complexes comprising the compound and labeled target protein, i.e. having a detectable moiety (see column 3, lines 62-67 and column 14, lines 19-24). Useful labels for the method and kit include biotin (see column 2, lines 14-17 and column 5, lines 11-23). Burmer discloses that the screening method finds use in pharmaceutical drug discovery and recovery for the development of lead compounds (see column 1).

Burmer differs from the instant invention in failing to disclose extracting and fractionating compounds from crude plant using chromatography.

Upadhyay et al. disclose fractionating and purifying a crude plant extract (Piper longum fruit) using a combination of solvent extraction and chromatographic methods. Repeated chromatography led to purification of four pure compounds which were separately screened for biological immunomodulatory activity (see columns 3 and 4).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to extract and fractionate compounds from crude plant as taught by Upadhyay for incorporation into a screening system and method for detecting biological activity as taught by Burmer because Upadhyay specifically taught that compounds are conventionally extracted and purified from plant sources for use in drug discovery screening assays and both of Burmer and Upadhyay specifically suggested using compounds extracted, purified, or isolated from plant to determine protein-ligand interaction for screening biological activity, i.e. immunomodulatory activity, in drug discovery of compounds.

6. Claims 16, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US Patent 6,087,103) in view of Upadhyay et al. (US Patent 5,962,515) as applied to claims 14, 15, 17, 19, 20, and 25-27 above, and in further view of Baek et al. (Agricultural Chemistry and Biotechnology, April 1998 (Abstract)) or Verma et al. (Journal of Medicinal and Aromatic Plant Sciences, September 1997).

Burmer and Upadhyay et al. have been discussed supra. Burmer Upadhyay et al. differ from the instant invention in failing to disclose that the plant extract is from an herb, which is Carthamus tinctorius.

Baek et al. teach extracting and fractionating compounds from Carthamus tinctorius. Two biologically active flavonoid compounds have been isolated by repeat silica gel column chromatographies.

Verma et al. teach extracting and isolating compounds from Carthamus tinctorius. According to Verma et al., these biologically active compounds from Carthamus tinctorius have antithrombotic capacity (see page 740).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to screen an extract of the plant C. tinctorius as taught by Baek or Verma for compounds with biological activity, i.e. antithrombotic activity, using the method and kit of Burmer as modified by Upadhyay, because both of Burmer and Upadhyay et al. specifically taught application of their simultaneous screening method for drug discovery of lead pharmacological compounds including those comprising small organic molecules such as those from plant extracts such as C. Tinctorius herbs as in the teaching of Baek or Verma.

7. Claims 18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US Patent 6,087,103) in view of Upadhyay et al. (US Patent 5,962,515) as applied to claims 14, 15, 17, 19, 20, and 25-27 above, and in further view of Kutsuna et al. (Journal of the Pharmaceutical Society of Japan, November, 1988) (Abstract)).

Burmer and Upadhyay et al. have been discussed supra. Burmer Upadhyay et al. differ from the instant invention in failing to teach that the protein target is a glycoprotein or a platelet membrane receptor protein.

Kutsuna et al. isolate, identify, and determine a biologically active compound from safflower Carthamus tinctorius. The compound is a platelet aggregation inhibitor which exhibits in vivo anti-thrombotic activity, and which inhibits glycoprotein (GPIIbIIIa)

binding to serum proteins. The compound is induced by adenosine diphosphate, and is identified as adenosine.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the protein taught in the method of Burmer as modified by Upadhyay with glycoprotein or a platelet membrane receptor protein as taught by Kutsuna to screen an extract of plant for compounds having biological activity, i.e. platelet aggregation inhibition, because Burmer and Upadhyay specifically taught application of his simultaneous screening method for drug discovery of lead pharmacological compounds including those comprising small organic molecules from plant extracts that are capable of platelet aggregation inhibition, affecting platelet membrane receptor glycoprotein IIb/IIIa as in the teaching of Kutsuna.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US 6,087,103) in view of Upadhyay et al. (US Patent 5,962,515) as applied to claims 14, 15, 17, 19, 20, and 25-27 above, and in further view of Baek et al. (Agricultural Chemistry and Biotechnology, April 1998 (Abstract)) or Verma et al. (Journal of Medicinal and Aromatic Plant Sciences, September 1997), and further in view of Kutsuna et al. (Journal of the Pharmaceutical Society of Japan, November, 1988) (Abstract)).

Burmer, Upadhyay et al., and Baek et al. or Verma et al. have been discussed supra. Burmer, Upadhyay et al. and Baek et al. or Verma et al. differ from the instant

invention in failing to disclose that the recovered compound has a molecular weight of 268 gm/mole and is self-polymerizable.

Kutsuna et al. isolate, identify, and determine a biologically active compound from safflower Carthamus tinctorius. The compound is a platelet aggregation inhibitor which exhibits in vivo anti-thrombotic activity, and which inhibits glycoprotein (GPIIbIIIa) binding to serum proteins. The compound is induced by adenosine diphosphate, and is identified as adenosine.

Kutsuna et al. is silent in teaching that the compound exhibiting platelet aggregation inhibition, has a molecular weight of 268 gm/mole and is self-polymerizable.

It is, however, maintained that inherent properties of an isolated active compound, i.e. molecular weight of 268 gm/mole and self-polymerizability, that has been identified in this case as adenosine, can be obtained using routine optimization procedures. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover optimum values of inherent properties by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). Accordingly, it would have been obvious for one of ordinary skill to have discovered the optimum values of inherent properties of isolated active compounds obtained in the method disclosed by Burmer and Upadhyay from plants or herbs such as C. tinctorius as taught by Baek or Verma, having biological activity as identified by Kutsuna, by normal optimization procedures.

Response to Arguments

9. Applicant's arguments with respect to claims 14-20 and 25-31 have been considered but are moot in view of the new grounds of rejection.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641

Gailene R. Gabel
Patent Examiner
Art Unit 1641
December 18, 2003